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Notices

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Public Health Service (PHS)

National Institutes of Health (NIH)

National Toxicology Program Office

National Toxicology Program; Availability of Technical Report on Toxicology and Carcinogenesis Studies of HC Yellow 4

58 FR 14219

DATE: Tuesday, **March** 16, 1993

[*14219]

The HHS' National Toxicology Program announces the availability of the NTP Technical Report on the toxicology and carcinogenesis studies of HC Yellow 4, used in semipermanent hair dyes.

Two-year toxicology and carcinogenesis studies were conducted by feeding groups of 70 male rats diets containing 0, 2,500 or 5,000 ppm HC Yellow 4 and feeding groups of 70 female rats and 70 mice of each sex diets containing 0, 5,000 or 10,000 ppm HC Yellow 4 for up to 2 years.

Under the conditions of these 2-year feed studies, there was equivocal evidence of carcinogenic activity n1 of HC Yellow 4 in male F344/N rats based on the increased incidence of pituitary gland adenomas and hyperplasia. The male rats may have been able to tolerate a slightly higher dose of the chemical. There was no evidence of carcinogenic activity of HC Yellow 4 in female F344/N rats given 5,000 or 10,000 ppm. There was no evidence of carcinogenic activity of HC Yellow 4 in male or female B6C3F1 mice given 5,000 or 10,000 ppm.

n 1 The NTP uses five categories of evidence of carcinogenic activity observed in each animal study: two categories for positive results ("clear evidence" and "some evidence"), one category for uncertain findings ("equivocal evidence"), and one category for no observable effect ("no evidence"), and one category for studies that cannot be evaluated because of major flaws ("inadequate study").

There was a chemical-related increase in the incidence of thyroid gland pigmentation and follicular cell hyperplasia in mice.

The study scientist for this bioassay is Dr. Kamal M. Abdo. Questions or comments about the contents of this Technical Report should be directed to Dr. Abdo at P. O. Box 12233, Research Triangle Park, NC 27709 or telephone (919) 541-7819.

Copies of Toxicology and Carcinogenesis Studies of HC Yellow 4 in F344/N Rats and B6C3F1 Mice (Feed Studies) (TR 419) are available without charge from Central Data Management, NIEHS, MD A0-01, P. O. Box 12233, Research Triangle Park, NC 27709; telephone (919) 541-3419 or (919) 541-1371.

Dated: March 10, 1993.

Kenneth Olden,

Director, National Toxicology Program.

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